REMARKS

I. Introduction

The Office Action mailed March 22, 2010, has been carefully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1, 9-10, 12, and 16-18 are pending. Claims 2-6, 7-8, 11, and 13-15 have been cancelled. Claim 1 has been amended. Support for the amendment is found, *inter alia*, in claim 7 as originally filed.

III. Summary of the Office Action

In the Office Action, the Examiner rejected the claims as follows:

1) claims 1, 7, 9-10, 12, and 16-18 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement; and

2) claims 1, 7, 9-10, 12, and 16-18 under 35 U.S.C. § 103(a) as being obvious over Doen et al. (U.S. 2003/0191157).

IV. Arguments

Applicant respectfully traverses the rejections for the following reasons:

A. The claims contain proper written description

Claims 1, 7, 9-10, 12, and 16-18 under stand rejected for failing to comply with the written description requirement. The Examiner alleges that the table on page 7 of the specification does not provide written support for "about" 1:0.359 and the "alkaline compounds." Applicants have amended claim 1 to remove the term "about" and to replace "alkaline compounds" with "sodium hydroxide."

The Examiner also alleges that the concept of a set ratio of rabeprazole to alkaline compound is not adequately supported by the original disclosure. The Examiner avers that the pH is the critical variable for stability, not the ratio of rabeprazole to alkaline compound. Applicants respectfully submit that the ratio is clearly supported by the table on page 7 of the specification. Further, because the present formulation does not use a buffer (as shown in the table on page 7), the amounts of sodium hydroxide and rabeprazole are critical in maintaining the proper pH. Accordingly, because those two components are the only two contributing to the pH, their ratio is critical in obtaining the desired pH and thus the desired stability. Therefore, one skilled in the art would conclude that the table on page 7 of the specification provides written support for the rabeprazole to sodium hydroxide ratio of 0.359.

B. The claims are not obvious

Claims 1, 7-10, 12, and 16-18 stand rejected as being obvious over Doen et al. Even though Applicants believe that the Examiner has failed to produce a *prima facie* case of obviousness, in the interest of compact prosecution, Applicants respectfully submit that the claimed invention produces

unexpected results sufficient to over come any *prima facie* case. Applicants filed a Declaration Under 37 C.F.R. §1.132 by Mr. Bharat Babulal Shah on December 15, 2009 ("December Declaration"), comparing a composition using the rabeprazole to alkaline compound ratio of the present invention (1:0.359) to the composition using the ratio taught by Doen et al. (1:1). The Examiner alleges that the December Declaration is insufficient. The Examiner alleges that "[i]t is not clear that the comparison of the two samples is a true side by side comparison of the prior art and the claimed composition." Office Action at 9. The two compositions presented in the December Declaration contain exactly the same ingredients except the amount of alkaline compound. The Examiner has recognized that the difference between the present invention and Doen et al. is the ratio of rabeprazole to alkaline compound. Because the rabeprazole amounts in the compositions of the December Declaration are the same, the only adjustable parameter to meet the ratios is the amount of the alkaline compound (sodium hydroxide). Further, the December Declaration specifies "other ingredients claimed in the present invention." By properly reading the claim, it is clear that other than rabeprazole and the alkaline compound, the other ingredients are mannitol and water for injection. Nevertheless, Applicants files herewith another Declaration Under 37 C.F.R. §1.132 by Mr. Bharat Babulal Shah ("Present Declaration") to clarify that the other ingredients claimed in the present invention include mannitol and water and to present the HPLC protocol used to determine the amount of rabeprazole. The protocol clearly specifies that the standard deviation is no more than 2%. Therefore, it is clear that the increased stability of the present invention is significant.

The Examiner also questions the practical benefit of the added stability, because "both samples are within the desired specification and injection usually occurs in a shorter time period

than one hour after reconstitution." Office Action at 9. This line of reasoning completely ignores the fact that the stability of the present invention allows for the production of multi injection vials. The ability for multiple injections has a clear practical benefit of reducing cost. Considering the soaring healthcare cost in the United States, that benefit is real, practical, desirable, and significant. Also of significance is the fact that the present invention uses lower amounts of sodium hydroxide than Doen et al. which results in less pain at the site of injection.

Therefore, for the reasons noted, Applicants respectfully submit that the present invention provides unexpected results when compared to Doen et al. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

Applicants have responded to the Office Action mailed March 22, 2010. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (125139.0101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Dated: August 23, 2010

Respectfully submitted,

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